

REMARKS

In response to the Office Action of August 7, 2007, claims 19, 47 and 53 have been amended and claim 59 has been added. Claims 47 and 53 were rejected under 35 U.S.C. § 112, first paragraph and claims 19-30, 32 and 46-58 were rejected under 35 U.S.C. § 103(a). Each of the rejections is addressed below.

As a preliminary matter claim 19 is herein amended to remove the limitations added in the Office Action Response dated May 9, 2007, in view of the Examiner's statements in the Office Action dated August 7, 2007, that such amendments did not confer patentability to the claim. Likewise, new claim 59, which is drawn to the subject matter of canceled claim 31, has been added.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

The first paragraph of Section 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971).

The Examiner has rejected claim 47 and 53 under the first paragraph of Section 112 on the basis that the Specification does not enable the prevention of diseases and conditions. Although Applicant does not acquiesce to this rejection, in the interest of furthering the prosecution of this case, independent claims 47 and 53 have been amended without prejudice by deleting prevention from the claims. Applicant reserves the right to prosecute claims directed to the deleted subject matter in a timely filed continuing application.

Rejections under 35 U.S.C. § 103(a)

The Examiner bears the burden of establishing a prima facie case of obviousness under 35 U.S.C. § 103. In determining obviousness, one must focus on Applicant's invention as a

whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991).

The primary inquiry is:

whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success Both the suggestion and the expectation of success must be found in the prior art, not in the applicant's disclosure.

In re Dow Chemical, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). To establish obviousness, both the elements of the claimed invention plus the motivation to combine the elements must be present in the prior art. *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (PTO Bd. App. Intf., 1988). Thus, if an element recited in the claims is not described in the cited prior art references, then *prima facie* obviousness is not established.

The Examiner has rejected claims 19-30, 32 and 46-58 under 35 U.S.C. § 103(a) as being unpatentable over Xu (U.S. Pat. No. 6,083,921) in view of Zhou (U.S. Pat. No. 6,319,523) for the reasons set forth in the Office Action dated February 9, 2007. Briefly, the Examiner reasons that Xu teaches a pharmaceutical composition comprised of baicalin for antibacterial purposes and Zhou teaches a pharmaceutical composition comprised of catechin for antibacterial purposes. From this, the Examiner concludes that one of ordinary skill in the art would have been motivated to modify Xu's pharmaceutical composition to include the active ingredient in Zhou's composition because the combined references would create an improved pharmaceutical composition. In response to this rejection, the claims of the instant invention have been amended to clarify that the composition of the instant invention is useful for the treatment of cyclooxygenase (COX) and lipoyxygenase (LOX) mediated diseases and conditions of the skin. Support for this amendment to the claims can be found throughout the Specification (see e.g. page 29, lines 3-4), which provides "[t]he present invention . . . includes methods for the prevention and treatment of COX and LOX mediated skin diseases and conditions."

Xu teaches pharmaceutical compositions for use in preventing and treating viral and bacterial infections or for use in enhancing the immune response by increasing NK cell activity or augmenting the production of interferon-alpha. It is noted in the Specification that

"[i]nterferon-alpha is an important cytokine in resisting viral infection" (col. 19, lines 51-52) and that NK cells "participate directly in eliminating viral infected cells as well as the viral particles itself" (col. 19, lines 56-58). It is further noted that "[t]hese two effects help form an effective immunobARRIER in resisting viral related illnesses." (col. 19, lines 59-61). Xu does not teach or suggest that any of the disclosed compositions and/or compounds would be useful in the treatment of skin conditions. Nor does Xu teach or suggest that any of the compositions and/or compounds disclosed function as inhibitors of COX and/or LOX or that any of the compositions and/or compounds would be useful in the treatment of COX and LOX mediated diseases or conditions. Rather, Xu teaches that the disclosed compositions "are particularly suitable for treating or preventing an infection by bacteria and other viruses that affect the respiratory system." (col. 8, lines 36-41). Furthermore, there is no evidence to suggest that there would any substantial overlap between indications requiring the use of the compositions taught by Xu and those requiring a COX/LOX inhibitor. The only teaching or suggestion regarding these compositions in general or *Scutellariae* specifically is as antibacterial, antiviral and immunomodulating substances.

Zhou teaches a composition for inhibiting oral bacteria comprised of a polyphenol derivative, preferably a catechin derivative and at least one compound selected from the group consisting of a mogroside derivative composition, licorice extract and combinations thereof (col. 1, lines 40-48). Zhou, like Xu does not teach or suggest that any of the disclosed compositions and/or compounds would be useful in the treatment of skin conditions. Nor does Zhou teach or suggest that any of the compositions and/or compounds disclosed function as inhibitors of COX and/or LOX or that any of the compositions and/or compounds would be useful in the treatment of COX and LOX mediated diseases or conditions. Rather, Zhou teaches that the disclosed compositions inhibit oral bacteria and are "effective in treating oral malodor and gum diseases, which helps prevent tooth decay and stomach acid reflux." (col. 1, line 64 - col. 2, line 1). Furthermore, as in the case of the Xu reference, there is no evidence to suggest that there would

any substantial overlap between indications requiring the use of the compositions taught by Zhou and those requiring a COX/LOX inhibitor.

As detailed above, the claims of the instant invention are drawn to a pharmaceutical composition of matter for use in the prevention and treatment of COX and LOX mediated diseases and conditions of the skin. Independent claims 1 and 47 have been amended to clarify that the use of said composition as an antimicrobial agent is not included within the scope of the claims. Independent claim 53 is drawn to the use said composition in the treatment of sunburns and skin damage resulting from exposure to UV radiation. Thus, the use of said composition as an antimicrobial agent is also not included within the scope of this claim. Xu and Zhou, on the other hand, teach compositions for use as antimicrobial agents. Neither of these references teaches or suggests the treatment of any of the specific diseases and conditions set forth in the Specification or claims of the instant invention. As noted above, to establish obviousness, both the elements of the claimed invention plus the motivation to combine the elements must be present in the prior art. *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (PTO Bd. App. Intf., 1988). Thus, if an element recited in the claims is not described in the cited prior art references, then *prima facie* obviousness is not established. As such, Applicant maintains that this combination of references does not render the claims of the instant invention obvious and respectfully requests that the Examiner reconsider this rejection.

Appl. No. 10/817,330
Amdt. dated November 19, 2007
Reply to Office Action of August 7, 2007

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

November 19, 2007

/Rosemary Kellogg/
Rosemary Kellogg, #39,726
Swanson & Bratschun, L.L.C.
8210 SouthPark Terrace
Littleton, Colorado 80120
Telephone: (303) 268-0066
Facsimile: (303) 268-0065

S:\ClientFolders\UniGen Pharmaceuticals\UNI26\UTILITY\UNI 26 OA 11-19.doc